research to date indicates that CMGs are effective predictors of resource use as measured by proxies such as length of stay and charges. The use of these proxies is necessary because data that measures actual nursing and therapy time spent on patient care, and other resource use data, are not available. The scientifically structured collection of data on patient characteristics and patient-specific resource use may enhance our ability to refine the CMGs in a manner that supports our policy objectives for implementing a IRF prospective payment system. Accordingly, we have contracted with Aspen Systems Corporation to collect actual resource use data in a sample of IRFs. The data collected by Aspen will be submitted to RAND for analysis to determine if it can be used to support future refinements to the CMGs.

III. The Minimum Data Set for Post-Acute Care (MDS–PAC) Patient Assessment Instrument

A. Implementation of the MDS–PAC

Under section 1886(j)(2)(D) of the Act, ''The Secretary is authorized to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the prospective payment system under this subsection.'' The collection of patient data is indispensable for the successful development and implementation of the IRF prospective payment system. A comprehensive, reliable system for collecting standardized patient assessment data is necessary for: (1) The objective assignment of Medicare beneficiaries to appropriate IRF CMGs; (2) the development of a system to monitor the effects of an IRF prospective payment system on patient care and outcomes; (3) the determination of whether future adjustments to the IRF CMGs are warranted; and (4) the development of an integrated system for post-acute care in the future.

The MDS–PAC is the standardized patient assessment instrument we are proposing to use under the IRF prospective payment system. We acknowledge that the nature of the patient data we would collect may evolve over time. We believe that the present structure of independent Medicare post-acute benefits, which includes payment systems, coverage requirements, and quality assessment instruments based primarily on site of care, may provide incentives that result in reduced access and choice for beneficiaries and may contribute to inappropriate care. As a result of this fragmentation in the payment and delivery of post-acute care under Medicare, we are reevaluating the payment and delivery of post-acute services with the objective of developing a more integrated approach focusing on the entire post-acute episode of care and each patient's care needs regardless of setting. We believe the MDS–PAC will help to move Medicare toward our long term objective of creating a more integrated post acute care payment and delivery system that facilitates improved quality, choice and access to care for beneficiaries.

Our goal of ultimately establishing a common system to assess patient characteristics and care needs for post-acute providers was endorsed by MedPAC in its March 1999 report to the Congress. MedPAC recommended that the Secretary collect a core set of patient assessment information across all post-acute settings. (Recommendation 5A). In the narrative supporting this recommendation, MedPAC ''commends HCFA's development of the MDS–PAC and encourages its refinement and use. The instrument will facilitate greatly comparisons of patient characteristics and service use across inpatient post-acute settings. Insights gleaned from these data should inform future prospective payment system policies, as well as longer term policy considerations about post-acute care.'' We share MedPAC's opinion of the utility of a common patient data system across post-acute settings. We believe that future refinements in the design and application of the MDS–PAC will provide us with essential information to inform policy decisions related to post-acute care users and their characteristics, quality, and payment.

The implementation of the per-case prospective payment system based on the ''functional-related group'' methodology requires the use of a standardized data collection instrument that contains the elements required to classify a patient into a distinct CMG. To classify a patient into a distinct CMG the data collection instrument must first assign the patient into one of the various high level categories that are based principally on ICD–9–CM diagnoses plus some additional patient information. These high level categories are called Rehabilitation Impairment Categories. After that initial classification step a patient's comorbidity data (which is also based on the ICD–9–CM codes), the level of the patient's impairment as determined by the patient's motor and cognitive function scores, and the age of the patient are used to classify a patient into a distinct CMG within the higher level Rehabilitation Impairment Group. Additional data elements are required to identify the patient and for monitoring the quality of care furnished to patients in IRFs.

Several approaches to the collection of these data elements are available. These include—(a) the development of a new data collection instrument, the MDS–PAC (as proposed in this rule); (b) adoption of an instrument closely modeled on the Uniform Data Set for Medical Rehabilitation (UDSmr) and the Caredata.com Clinical Outcome Set (COS) that would contain the needed data elements exactly as they have been recorded in the past and as used in the development of the FIM–FRG classification of patients; and (c) the incorporation verbatim into the new instrument (MDS–PAC) of the UDSmr/COS data elements that are relevant to payment. We are proposing the first option, the MDS–PAC, for the reasons outlined in the section below.

1. Use of MDS as Foundation

The basis of the MDS–PAC system is the Minimum Data Set (MDS)/Resident Assessment Instrument (RAI). The MDS/RAI was one of the key provisions of the nursing home reform legislation enacted by the Omnibus Budget Reconciliation Act of 1987 (OBRA), Pub. L. 100–203, and the first standardized assessment instrument that the Congress required to be used in a post-acute care setting. The MDS is a core set of screening and assessment elements, including common definitions and coding categories, which forms the foundation of a comprehensive assessment (the RAI). OBRA mandated that we develop the MDS and require its use for all residents of certified long-term care facilities as a condition of participating in Medicare or Medicaid.

We originally implemented the MDS/RAI in 1990 through 1991 in the approximately 17,000 certified long-term care facilities nationwide. The MDS/RAI has been used by long-term care facilities to assess all residents at specific points during their stay, regardless of payer source. Residents are assessed upon admission to the facility, after experiencing a significant change, and at least annually, with a review of key items required every 90 days. Regulations requiring all certified long-term care facilities to encode and transmit MDS data to the State and HCFA became effective June 22, 1998 ((62 FR 67174) ''Resident Assessment In Long Term Care Facilities''). As of March 3, 2000, there were 23,829,196 records for 4,576,748 residents submitted to our national MDS repository.

Long-term care facilities use the assessment system as the basis of developing an individualized plan of care. However, the design of our long-term care facility payment and quality of care systems relies on use of the resident characteristic, health status, and service use information derived from the MDS to support a number of our programs. For example, the SNF prospective payment system implemented in July 1998 relies on MDS data to classify patients into the appropriate case-mix categories. In addition, in July 1999, we began to use MDS data to generate quality indicators for use in the long-term care facility survey process. Also, long-term care facilities may request real-time MDS-based quality indicator reports, from the HCFA-sponsored State-level MDS data system, that compare the facility's performance in key care areas with the performance of other facilities within the State. These reports can be used for internal quality assurance and improvement activities. Our Peer Review Organizations (PROs) are using MDS data to conduct long-term care facility quality improvement activities in a number of areas, including pain management, pressure ulcers, and urinary incontinence.

In keeping with our commitment to the nursing home industry to refine the MDS/RAI system over time to incorporate advances in assessment technology and changes in the nursing home population, we developed a second generation instrument, known as the MDS version 2. The MDS 2 was implemented nationally in 1996. Shortly thereafter, we agreed to begin work on a post-acute version of the MDS, in response to the long-term care industry's concerns that the MDS had not been constructed to address the characteristics and needs of the increasing numbers of short stay patients admitted to SNFs for rehabilitation and medically complex care.

Before we started work on the MDS–PAC, however, we made a policy decision that our goal was to establish a common instrument to assess patients receiving services by all Medicare institutional post-acute providers. This broadened the scope of the instrument to include freestanding rehabilitation hospitals and hospital-based rehabilitation units, as well as long-term care hospitals. Our policy decision was based on a belief that there is considerable overlap among the patient populations and services rendered by post-acute care providers. The March 1999 MedPAC report to Congress indicated that prior distinctions in the types of patients and services provided across settings have become less clear for a number of reasons (p. 82), and that lack of uniform patient-level data across settings severely restricts our ability to identify where differences and overlaps occur.

This hypothesis regarding the overlap of patient populations was tested by collecting MDS 2 data for patients of rehabilitation and long-term care hospitals and comparing that data with MDS records for SNF patients. The SNF database included records for long-stay nursing home residents who had been readmitted after a hospitalization and now qualified for a period of skilled care. There were 1,535 SNF patient records collected from initial MDS assessments in 1996. Of these patient records, 517 (34 percent) of the patients were expected to be discharged within 30 days of admission. An additional 248 (16 percent) were expected to be discharged in 31 to 90 days. For the remaining patient records, discharge status was unknown, not anticipated or (in a limited number of cases) the discharge variable was missing. This activity was also conducted in order to provide us with information about the characteristics, health status, and service utilization of rehabilitation and long-term care hospital patients, as part of our initial activities to inform development of the MDS–PAC.

Staff from participating rehabilitation hospitals, rehabilitation units of acute care hospitals, and long-term care hospitals were trained in the use of the MDS 2.0, and were asked to complete it for a sample of their newly admitted patients during June through October 1998. Data were received for 614 patients in 26 rehabilitation hospitals and units, and for 479 patients in 26 long-term care hospitals. Of the 52 providers participating in the baseline data collection, 38 were recruited using a random sample of Medicare-certified providers.

We found many similarities in the characteristics, health status, medical diagnoses, and service utilization patterns of SNF and rehabilitation hospital patients. We note that our focus groups indicated to us that many rehabilitation hospitals and self-proclaimed ''subacute'' SNFs have as a criteria for admission the patient's potential ability to be discharged from the facility within a certain time period. Thus, for comparative purposes we differentiated between the MDS records of SNF patients expected to be discharged and those of SNF patients not expected to be discharged. As illustrated below by Table 1C, patients in rehabilitation hospitals and SNF patients who were expected to be discharged demonstrated similar levels of activity of daily living (ADL) overall impairment, as measured by the MDS 2, while a greater number of SNF patients who were not expected to be discharged experienced impairment in ''late loss'' ADLs or were fully dependent.

TABLE 1C.—PERCENT OF PATIENTS WITH ADL IMPAIRMENT BY FACILITY TYPE

ADL score (hierarchical)	LTC hospital	Rehab hospital	SNF discharge expected	SNF discharge not expected
0—Independent	3.1	.8	4.2	3.4
1—Supervision	4.4	9.5	6.5	5.6
2—Limited	12.8	25.4	29.3	17.9
3—Early Loss ADL—extensive or dependent	4.2	14.8	8.2	9.8
4—Mid late loss ADL—extensive assistance late loss ADL	8.0	21.1	20.9	15.9
5—Mid late-some late loss ADL dependency	34.8	22.5	27.3	33.8
6—Full dependency	32.9	5.9	3.7	13.5

In addition, fewer SNF patients were reported to have symptoms of delirium as compared to rehabilitation hospital patients. While the number of SNF patients not expected to be discharged who experienced memory problems was higher, the overall cognitive performance score (a composite measure based on several MDS items) for patients across the four populations was remarkably similar, except for the higher number of long-term care hospital patients rated as a ''6'' (that is, very severely cognitively impaired). A comparison of cognitive impairment by facility type can be seen in Table 2C.

TABLE 2C.—PERCENT OF PATIENTS WITH COGNITIVE IMPAIRMENT BY FACILITY TYPE

Condition	LTC hospital	Rehab Hospital	SNF discharge expected	SNF discharge not expected
Delirium Symptoms—New				
Easily Distracted	12.0	15.4	3.1	1.7
Altered Perceptions	9.7	5.9	2.6	2.2
Disorganized Speech	8.8	10.5	2.4	2.2
Restlessness	13.6	8.9	2.0	3.0
Lethargy	14.4	9.2	4.0	4.0
Mental Function Varies	17.2	13.5	5.2	4.0
Cognitive Performance Scale				
0=Intact	40.5	49.3	46.0	17.9
1=Borderline Intact	14.3	13.6	16.7	17.6
2=Mild	7.2	10.2	12.0	11.3
3=Moderate	9.1	13.0	16.3	26.2
4=Moderate Severe	4.0	3.3	4.1	10.5
5=Severe	3.0	5.7	3.3	6.9
6=Very Severe	21.9	4.9	1.6	9.6
Memory				
Memory Problem—short term	32.8	36.2	37.0	61.0
Memory Problem—long-term	29.9	23.0	23.1	46.2
Memory Problem—situational	37.5	12.4		

We did not find significant differences across care settings in many of the disease diagnoses recorded in section I of the MDS, although long-term care hospital patients had more cases of diabetes, cardiac dysrhythmia, post heart surgery, peripheral vascular disease, paraplegia, respiratory conditions, renal failure, and antibiotic-resistant infections (Table 3C).

TABLE 3C.—PERCENT OF PATIENTS WITH SPECIFIC CONDITIONS BY FACILITY TYPE

Condition	LTC hospital	Rehab hospital	SNF discharge expected	SNF discharge not expected
Diseases				
Diabetes	37.0	25.0	27.0	24.2
Hyperthyroidism	0.4	0.7	0.7	0.3
Hypothyroidism	9.0	8.2	8.0	6.8
Arteriosclerotic heart disease	17.3	14.7	15.7	18.3
Cardiac dysrhythmia	21.1	11.3	14.7	17.2
Post heart surgery	24.0	13.0	6.9	6.2
CHF	23.0	8.5	21.6	22.9
Deep vein thrombosis	4.8	3.1	11.4	1.8
Hypertension	37.6	45.8	47.9	46.5
Hypotension	2.8	1.3	1.5	1.0
Peripheral vascular disease	15.0	9.0	8.6	6.0
Other cardiovascular disease	14.8	10.3	19.5	20.8
Arthritis	11.3	20.1	25.4	21.9
Hip fracture	6.7	11.6	14.1	7.4
Missing limb	5.4	4.9	3.0	3.5
Osteoporosis	7.1	3.6	8.0	10.5
Pathological bone fracture	1.3	1.8	1.0	1.5
Alzheimer's	1.5	0.5	4.1	12.3
Aphasia	2.3	6.5	3.8	7.2
CP	0.2	0.7	.....	.....
CVA	23.8	34.6	22.2	27.7
Other dementia	7.9	2.1	13.9	31.5
Hemiplegia/hemiparesis	12.9	27.8	8.8	10.1
MS	2.1	1.1	0.1	0.7
Paraplegia	3.0	2.1	0.3	0.3
Parkinson's	2.5	1.6	3.3	4.0
Quadriplegia	3.3	2.6	0.1	0.2
Seizure disorder	6.5	5.2	4.5	4.5
TIA	1.0	23	4.0	4.0
Traumatic brain injury	4.2	7.0	0.3	0.3
Anxiety disorder	4.6	5.2	7.8	6.8
Depression	10.2	14.4	14.6	13.6
Manic depression	0.8	1.1	0.9	0.7

TABLE 3C.—PERCENT OF PATIENTS WITH SPECIFIC CONDITIONS BY FACILITY TYPE—Continued

Condition	LTC hospital	Rehab hospital	SNF discharge expected	SNF discharge not expected
Schizophrenia	0.8	0.5	1.0	1.5
Asthma	3.5	3.1	2.0	1.5
Emphysema/COPD	29.0	10.1	19.3	17.2
Pulmonary failure	24.0	4.3	.....	.....
Cataracts	2.9	3.3	6.5	5.5
Diabetic retinopathy	1.9	1.8	0.7	0.5
Glaucoma	3.8	2.9	5.9	4.0
Macular degeneration	1.5	0.7	1.2	0.8
Allergies	9.4	15.2	28.2	28.9
Anemia	15.7	11.9	18.2	19.5
Cancer	12.1	7.5	14.4	15.3
Renal failure	14.0	4.7	4.9	5.3
Amputated limb	5.4	5.0	N/A	N/A
Post surgery—elective hip	4.0	13.0	.....	.....
Antibiotic resistant infection	16.7	2.8	1.0	0.5
Pneumonia	19.2	3.1	8.5	6.5
UTI	21.9	19.9	21.1	23.1
Bladder Continence				
Continent, no catheter	28.0	60.9	63.4	45.6
Continent, catheter	52.1	15.2	N/A	N/A
Some incontinence	50.8	31.6	36.6	54.4
Bowel Continence	48.0	75.0	71.3	47.9
Complications				
Inability to lie flat—loss of breath	44.0	6.5	6.9	6.2
Shortness of breath—exertion	52.0	21.7	.....	.....
Shortness of breath—at rest	32.0	0.0	.....	.....
Difficulty coughing/clearing airways	40.0	2.2	N/A	N/A
Recurrent respiratory infection	28.0	2.2	.....	.....
Surgical wound	48.0	56.5	.....	.....
Pain				
None	45.4	25.6	36.0	58.8
Less than daily	17.3	19.5	31.0	22.3
Daily	37.3	55.0	33.0	18.9
Health Complications				
Syncope	2.3	1.0	.07	0
Unsteady Gait	26.2	52.5	48.0	40.1
Limited ROM—Arm	20.7	9.3	6.3	12.5
Limited ROM—Hand	18.0	7.2	3.5	8.8
Limited ROM—Foot	26.4	10.5	5.7	14.7
Pressure Ulcers—Any (stage 1–4)	36.0	17.9	17.7	21.6
Expectations (Rehabilitation Potential)				
Patient believes self could be more independent	53.7	74.5	45.1	16.2
Staff believes patient could be more independent	59.1	76.4	50.9	31.3
Patient able to perform tasks slowly	26.1	33.9	12.7	12.4
Major difference in ADLs AM and PM	8.1	16.7	1.9	3.2
Behavior				
Wander	3.6	4.1	2.8	9.1
Verbally abusive	3.4	3.8	3.0	5.4
Physically abusive	1.8	2.1	1.4	5.9
Socially inappropriate	3.2	4.8	4.2	8.6
Resists care	12.2	8.6	9.8	16.3

The diagnostic profiles of patients in rehabilitation hospitals and SNFs were similar, although rehabilitation hospitals treated a higher percentage of patients with strokes, hemiplegia/hemiparesis, and traumatic brain injury and fewer patients with congestive heart failure and emphysema or chronic obstructive pulmonary disease. Both bladder and bowel continence levels were similar for rehabilitation hospital and SNF patients who were expected to be discharged. Pain levels for rehabilitation hospital and SNF patients were also similar overall, although more

SNF patients were reported to experience pain less frequently than daily and more rehabilitation hospital patients were assessed as having daily pain. Pressure ulcer rates for rehabilitation hospital and SNF patients were comparable, as were the number of patients with unsteady gait and limitations in range of motion. Rehabilitation hospitals reported a higher use of restraints. Rehabilitation hospital and SNF patients who were expected to be discharged had a similar number of behavioral symptoms, which were less overall as compared to the number of behavioral symptoms experienced by SNF patients not expected to be discharged.

These results confirmed anecdotal information reported by rehabilitation hospital and SNF clinicians during our focus groups. While Medicare coverage policies allow payment to SNFs for a wider range of patients than rehabilitation hospitals, both groups reported that their patient populations had changed over the past few years, leading to some convergence in the types of patients treated by rehabilitation hospitals and SNFs. Both reported a large increase in the number of comorbidities and clinical complexities for patients admitted primarily for rehabilitative services, saying that ''uncomplicated'' patients were no longer admitted for inpatient rehabilitation, (instead, for example, ''uncomplicated'' patients requiring rehabilitation after a hip fracture now generally receive therapy in their homes).

It is our view that any system used to classify rehabilitation patients should be based on the same measures of a patient's health status and care needs as are used in other segments of the post-acute care industry. However, for purposes of this proposed rule, we are most concerned that the classification instrument work well with IRF patients. Given our use of the MDS in SNFs, it is logical to extend an MDS-based system to IRFs.

We are developing version 3 of the MDS/RAI, which we envision as containing sections for specific populations (for example, traditional, long stay resident; short-stay patient; those receiving palliative or end of life care; and pediatrics).

2. Other Options

We recognized that many rehabilitation hospitals already use a patient assessment instrument that contains the functional independence measures (FIM). The FIM were developed by researchers who were funded by a consortium of rehabilitation professional associations and the Department of Education, at the State University of New York (SUNY) at Buffalo in the 1980s. The FIM are contained in a patient assessment instrument that is marketed by the Uniform Data System for Medical Rehabilitation (UDSmr) maintained by SUNY/Buffalo. Caredata.com Clinical Outcome System (COS) used to market a patient assessment instrument that contained the FIM, but we have been notified that Caredata.com has discontinued its business related to FIM reporting as of July 2000. The patient assessment instrument marketed by UDSmr is proprietary.

Many rehabilitation providers are clients of UDSmr. Our 1997 data shows that approximately 68 percent of Medicare patients had a UDSmr or COS data file, indicating that these patients were assessed with the FIM. There is extensive experience with the FIM contained in the UDSmr and COS patient assessment instruments and the uses of the FIM data. This is documented by a substantial list of publications produced both in the United States and overseas (for example, Sweden and Japan), by the developers of the system, and by independent investigators.

The developers of the FIM offer a certification course to train assessors in the use of the instruments. This results in very high rates of intra and inter rater reliability, with Cronbach alpha coefficients of more than 0.9 for both the motor and cognitive subscores. The Cronbach alpha coefficient is a statistical measure of inter-rater reliability with perfect reliability equal to 1.0. Therefore, a score of 0.9 indicates a very high level of inter-rater reliability.

The MDS-PAC is a modification of the MDS, the patient assessment instrument developed for use in nursing facilities. The principal objective of the MDS is to facilitate care planning through a description of the needs of the patient for services. In contrast, the principal objective of the FIM is to assess person level disability in the inpatient medical rehabilitation setting.

The strength of the FIM assessment instrument is that it is a well-evolved and extensively tested approach to the assessment of the critical components of care provided by IRFs, the impact on the patient improvement in functional capacity, and the purpose of the care provided by the IRFs. The variations among facilities in the difference between the observed and expected improvement in function are used as indicators of the quality and the effectiveness of the facilities. The organization that analyzes FIM data for providers generates benchmark data that allows IRFs to compare the outcome of their performance on the functional independence measures relative to other providers participating in the system.

One drawback of the FIM assessment instrument is that it is specifically focused on functional performance. Information is collected only on the matters directly related to functional performance and only at admission and discharge, and, when possible, 6 months after discharge. There is, therefore, a lack of detail on the needs of the patient or on the evolution of the condition of the patient during the course of the admission. However, given that the mean length of stay in an IRF is 15.81 days (median length of stay is 14 days), we are specifically soliciting comments on the benefits of mid-stay assessments.

We are not proposing to use the FIM assessment instruments marketed by either the UDSmr or COS as the basis for an IRF prospective payment, because of our desire to have a common measurement instrument across different post-acute provider settings. Our proposal to use an MDS-based approach comes from our conviction that the use of common item labels and definitions across different provider settings would be essential to monitoring patient care across different provider settings. While we recognize that there are differences between the MDS and the MDS–PAC, our intention is, at some point in the future, to reconcile these differences. Structuring the IRF assessment instrument consistent with the MDS would allow for comparison of patients across different institutional settings. The MDS–PAC collects information on many of the same activities or functional measures as the FIM but defines these activities more specifically in some cases. It would also help facilitate continuity of care in that comparable baseline data would accompany the patient's transfer from one setting to the other. Standardized information across provider types would also be extremely useful in comparing patient characteristics and potentially the appropriateness of care in different settings that serve the same populations. This is especially important since analysis by RAND (1997) shows that costs for the same services vary significantly by provider.

When we began to develop the MDS in the 1980s, the possibility of using the FIM ADL scoring schema was considered. However, field experience demonstrated that nursing home staff did not feel comfortable making the level of distinctions required in the FIM.